

THE LANCET

Infectious Diseases

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed.
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Supplementary Appendix

Supplementary Methods

Study Design

A test negative case control design was used to estimate vaccine effectiveness against symptomatic disease and hospitalisation with Omicron sub-lineages BA.1 and BA.2 in individuals aged 18 years and older. The odds of vaccination in symptomatic PCR positive cases was compared to the odds of vaccination in symptomatic individuals who tested negative for SARS-CoV-2 in England.

Data Sources

COVID-19 Testing Data

SARS-CoV-2 Testing PCR testing for SARS CoV-2 in England is undertaken by hospital and public health laboratories (Pillar 1), as well as by community testing (Pillar 2). Pillar 2 testing is available to anyone with symptoms consistent with COVID-19 (high temperature, new continuous cough, or loss or change in sense of smell or taste), anyone who is a contact of a confirmed case, care home staff and residents, and to those who have self-tested as positive using a lateral flow test (LFT). Data on all positive PCR and LFTs, and on negative Pillar 2 PCR tests from symptomatic individuals with a test date after 25 November 2020 were extracted up to 31 March 2022. Individuals who reported symptoms and were tested in Pillar 2 between 17 January 2022 and 31 March 2022 were included in the analysis to estimate VE against symptomatic disease (Supplementary Figure 1). Any negative tests taken within 7 days of a previous negative test, and any negative tests where symptom onset date was within the 10 days or a previous symptoms onset date for a negative test were dropped as these likely represent the same episode. Negative tests taken within 21 days of a subsequent positive test were also excluded as chances are high that these are false negatives. Positive and negative tests within 90 days of a previous positive test were also excluded; however, where participants had later positive tests within 14 days of a positive then preference was given to PCR tests and symptomatic tests. For individuals who had more than one negative test, one was selected at random in the study period. Data were restricted to persons who had reported symptoms and gave a symptom onset date within the 10 days before testing to account for reduced PCR sensitivity beyond this period in an infection event.

Vaccination Data

The National Immunization Management System (NIMS) contains demographic information on the whole population of England who are registered with a general practice physician in England and is used to record all COVID-19 vaccinations. NIMS was accessed for dates of vaccination and manufacturer, sex, date of birth, ethnicity, and residential address. Addresses were used to determine index of multiple deprivation quintile and were also linked to Care Quality Commission registered care homes using the unique property reference number. Data on geography (NHS region), risk group status, clinically extremely vulnerable status, and health/social care worker were also extracted from the NIMS. Clinical risk groups included a range of chronic conditions as described in the Green Book (1), whereas the clinically extremely vulnerable group included persons who were considered to be at the highest risk for severe COVID-19, including those with immunosuppressed conditions and those with severe respiratory disease. Booster doses were identified as a third dose given at least 84 days after a second dose and administered after 13 September 2021. Individuals

with four or more doses of vaccine, heterologous primary schedule or fewer than 19 days between their first and second dose were excluded.

Testing data were linked to NIMS on 4 March 2022 using combinations of the unique individual National Health Service (NHS) number, date of birth, surname, first name, and postcode using deterministic linkage – 99.6% of eligible tests could be linked to the NIMS.

Identification of Delta and Omicron Variants and assignment to cases

Sequencing of PCR positive samples is undertaken through a network of laboratories, including the Wellcome Sanger Institute. Whole-genome sequences are assigned to UKHSA definitions of variants based on mutations (2). S-gene target status on PCR-testing is an alternative approach for identifying each sub-lineage because BA.1 has been associated with S-gene target failure on PCR testing with the Taqpath assay while BA.2 has been associated with a positive S-gene target. Cases were defined as BA.1 or BA.2 based on whole genome sequencing or S-gene target status, with sequencing taking priority. Where subsequent positive tests within 14 days included sequencing or S-gene target failure information, this information was used to classify the variant.

Hospital Admission Data

SUS is the national electronic database of hospital admissions that provides timely updates of ICD-10 codes for completed hospital stays for all NHS hospitals in England. Up to 24 ICD-10 diagnoses fields can be completed in SUS for each admission with the first diagnosis field indicating the primary reason for admission. Hospital inpatient admissions for a range of acute respiratory illnesses were identified from SUS and were linked to the testing data on 4 March 2022 using NHS number and date of birth as previously described (3). For the Pillar 2 samples, admissions with an ICD-10 acute respiratory illness (ARI) discharge diagnosis in the first diagnosis field were identified where the sample was taken 14 days before and up to 2 days after the day of admission. For the Pillar 1 samples, admissions with an ICD-10 coded ARI discharge diagnosis in any diagnosis field were identified where the sample was taken 1 day before and up to 2 days after the admission. Length of stay was calculated as date of discharge – date of admission. Where multiple admissions linked to the same sample date the first admission after the sample date was retained and episode length calculated by summing the stay length for each admission. Data were restricted to those with ARI in the first diagnosis field and where the length of stay was at least two days. The data was restricted to tests up to 16 March 2022 to account for delays in the SUS data recording.

Control selection

For analyses involving hospitalised controls any negative tests that led to a hospitalisation within 21 days of a previous hospital negative test were excluded. A maximum of one negative test per person within each of the following approximate 3-month periods was selected at random: 26 April to 1 August 2021, 2 August 2021 to 21 November 2021, 22 November 2021 to 16 March 2022. For analyses involving all Pillar 2 symptomatic controls the same was done within this control group.

Statistical Analysis

Logistic regression was used, with the PCR test result as the dependent variable and cases being those testing positive (stratified in separate analyses as either BA.1 or BA.2) and controls being those testing negative. Vaccination status was included as an independent variable and effectiveness defined as 1- odds of vaccination in cases/odds of vaccination in controls.

Vaccine effectiveness was adjusted in logistic regression models for age (ages 18-19, then 20 through to 89 in five-year bands, then everyone age 90 years or older), sex, index of multiple

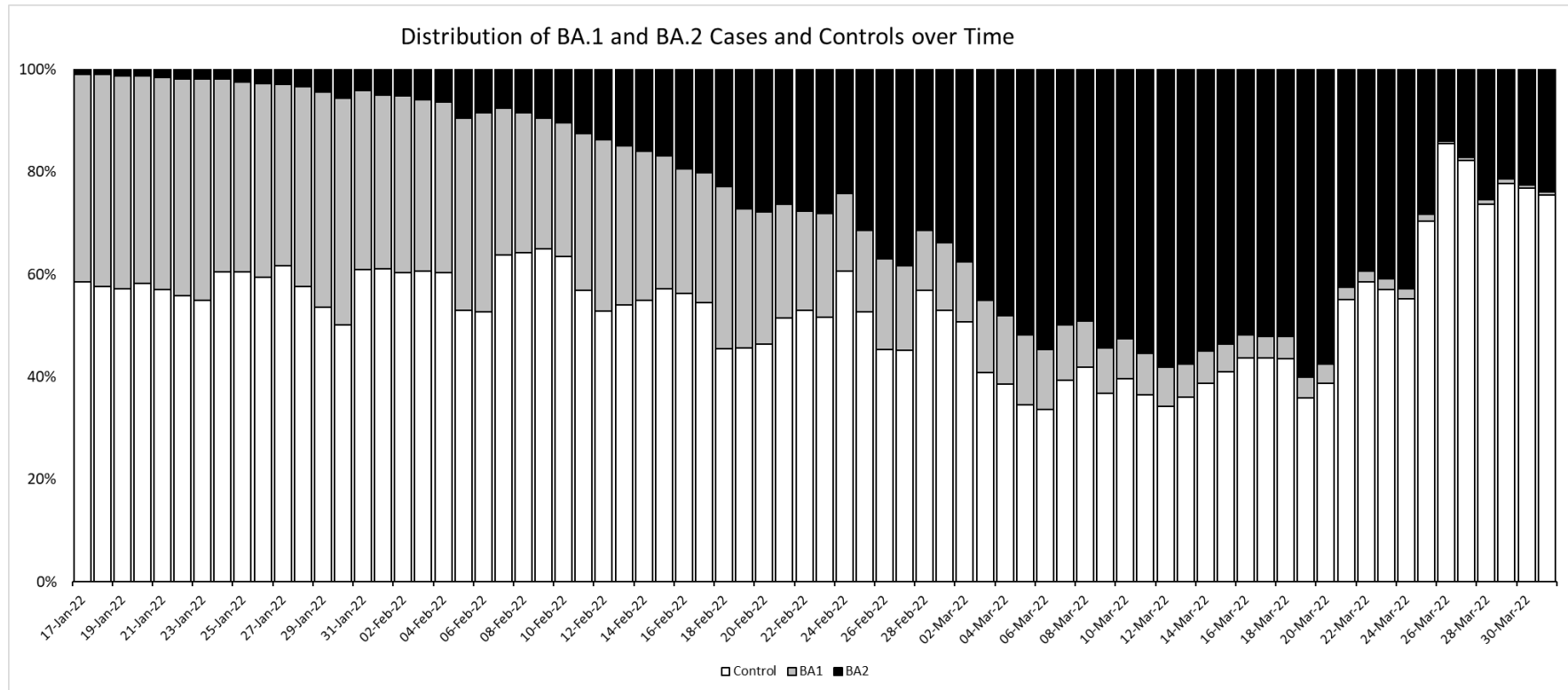
deprivation (quintile), ethnic group, history of travel, geographic region (NHS region), period (week of test), health and social care worker status, clinical risk group status, clinically extremely vulnerable, and previously testing positive. These factors were all considered potential confounders so were included in all models.

Analysis combined all vaccine manufacturers (ChAdOx1, BNT162b2 or mRNA-1273 for one dose or two doses, and BNT162b2 or mRNA-1273 (half-dose) for booster doses). Heterologous primary schedules and ChAdOx1 primary course followed by ChAdOx1 booster dose recipients were excluded.

Vaccine effectiveness was assessed in intervals of less than 4 weeks and 4 or more weeks post the first dose; less than 2 weeks, 2 to 24 weeks, and 25 or more weeks post the second dose; and less than 1 week, 1 week, 2 to 4 weeks, 5 to 9 weeks, 10 to 14 weeks and 15 or more weeks post a booster dose.

Supplementary Tables and Figures

Supplementary Figure 1. The distribution of eligible tests from BA.1 cases, BA.2 cases and controls over time.



Supplementary Table 1. Descriptive characteristics of eligible tests from symptomatic individuals.

			Overall		Negative		BA.1		BA.2	
			n	%	n	%	n	%	n	%
Vaccination Status and intervals after vaccine	Test Result	Interval (weeks)	1,127,517	100.0%	615,628	54.6%	265,820	23.6%	246,069	21.8%
	Unvaccinated		97,073	8.6%	37,280	6.1%	33,961	12.8%	25,832	10.5%
	Dose 1 *	<4	3,681	0.3%	2,086	0.3%	1,229	0.5%	366	0.1%
		4+	27,639	2.5%	14,414	2.3%	7,608	2.9%	5,617	2.3%
	Dose 2 *	<2	1,824	0.2%	1,189	0.2%	434	0.2%	201	0.1%
		2-24	75,122	6.7%	39,555	6.4%	25,444	9.6%	10,123	4.1%
		25+	106,940	9.5%	46,958	7.6%	33,616	12.6%	26,366	10.7%
	Booster**	<1	4,969	0.4%	2,751	0.4%	1,785	0.7%	433	0.2%
		1	7,909	0.7%	5,541	0.9%	1,989	0.7%	379	0.2%
		2-4	74,934	6.6%	51,990	8.4%	20,352	7.7%	2,592	1.1%
		5-9	261,881	23.2%	168,627	27.4%	67,466	25.4%	25,788	10.5%
		10-14	257,056	22.8%	143,890	23.4%	43,743	16.5%	69,423	28.2%
		15+	208,489	18.5%	101,347	16.5%	28,193	10.6%	78,949	32.1%
Age	18-19		27,899	2.5%	16,920	2.7%	6,700	2.5%	4,279	1.7%
	20-24		95,001	8.4%	55,013	8.9%	22,282	8.4%	17,706	7.2%
	25-29		128,276	11.4%	71,663	11.6%	30,575	11.5%	26,038	10.6%
	30-34		152,790	13.6%	84,679	13.8%	37,286	14.0%	30,825	12.5%
	35-39		151,014	13.4%	82,908	13.5%	38,371	14.4%	29,735	12.1%
	40-44		132,936	11.8%	72,227	11.7%	33,595	12.6%	27,114	11.0%
	45-49		111,498	9.9%	60,768	9.9%	26,680	10.0%	24,050	9.8%
	50-54		101,049	9.0%	54,411	8.8%	22,686	8.5%	23,952	9.7%
	55-59		83,166	7.4%	43,718	7.1%	18,243	6.9%	21,205	8.6%
	60-64		58,454	5.2%	30,392	4.9%	12,371	4.7%	15,691	6.4%
	65-69		36,142	3.2%	19,207	3.1%	7,020	2.6%	9,915	4.0%
	70-74		25,386	2.3%	12,678	2.1%	5,001	1.9%	7,707	3.1%
	75-79		12,507	1.1%	5,877	1.0%	2,509	0.9%	4,121	1.7%
	80-84		5,977	0.5%	2,732	0.4%	1,243	0.5%	2,002	0.8%
	85-89		3,358	0.3%	1,581	0.3%	725	0.3%	1,052	0.4%
	>=90		2,064	0.2%	854	0.1%	533	0.2%	677	0.3%
Gender	Female		698,771	62.0%	392,185	63.7%	161,032	60.6%	145,554	59.2%
	Male		426,669	37.8%	222,247	36.1%	104,335	39.3%	100,087	40.7%
	Missing		2,077	0.2%	1,196	0.2%	453	0.2%	428	0.2%
Ethnicity	African		11,893	1.1%	6,669	1.1%	2,874	1.1%	2,350	1.0%
	Any other Asian background		20,519	1.8%	11,198	1.8%	5,012	1.9%	4,309	1.8%
	Any other Black background		4,979	0.4%	2,666	0.4%	1,261	0.5%	1,052	0.4%
	Any other White background		104,522	9.3%	48,961	8.0%	30,267	11.4%	25,294	10.3%
	Any other ethnic group		23,244	2.1%	12,147	2.0%	6,138	2.3%	4,959	2.0%
	Any other mixed background		7,602	0.7%	4,104	0.7%	1,851	0.7%	1,647	0.7%
	Bangladeshi or British Bangladeshi		6,675	0.6%	3,614	0.6%	1,884	0.7%	1,177	0.5%
	British, Mixed British		758,109	67.2%	422,599	68.6%	170,317	64.1%	165,193	67.1%
	Caribbean		5,513	0.5%	2,662	0.4%	1,511	0.6%	1,340	0.5%

	Chinese	8,257	0.7%	4,695	0.8%	1,634	0.6%	1,928	0.8%
	Indian or British Indian	35,501	3.1%	20,720	3.4%	7,890	3.0%	6,891	2.8%
	Irish	6,966	0.6%	3,949	0.6%	1,347	0.5%	1,670	0.7%
	Pakistani or British Pakistani	21,393	1.9%	11,538	1.9%	7,226	2.7%	2,629	1.1%
	White and Asian	3,813	0.3%	2,198	0.4%	848	0.3%	767	0.3%
	White and Black African	2,487	0.2%	1,331	0.2%	636	0.2%	520	0.2%
	White and Black Caribbean	3,515	0.3%	1,808	0.3%	924	0.3%	783	0.3%
	Missing	102,529	9.1%	54,769	8.9%	24,200	9.1%	23,560	9.6%
NHS Region	East of England	154,515	13.7%	78,286	12.7%	39,259	14.8%	36,970	15.0%
	London	171,459	15.2%	89,904	14.6%	38,884	14.6%	42,671	17.3%
	Midlands	192,043	17.0%	107,429	17.5%	49,114	18.5%	35,500	14.4%
	North East	169,333	15.0%	86,652	14.1%	48,948	18.4%	33,733	13.7%
	North West	154,894	13.7%	68,188	11.1%	42,397	15.9%	44,309	18.0%
	South East	175,219	15.5%	110,444	17.9%	29,893	11.2%	34,882	14.2%
	South West	110,050	9.8%	74,722	12.1%	17,325	6.5%	18,003	7.3%
	Missing	4	0.0%	3	0.0%	0	0.0%	1	0.0%
IMD Quintiles	1	193,641	17.2%	95,522	15.5%	58,316	21.9%	39,803	16.2%
	2	220,423	19.5%	117,642	19.1%	54,900	20.7%	47,881	19.5%
	3	231,790	20.6%	127,715	20.7%	53,007	19.9%	51,068	20.8%
	4	237,148	21.0%	132,810	21.6%	51,106	19.2%	53,232	21.6%
	5	240,195	21.3%	139,536	22.7%	47,446	17.8%	53,213	21.6%
	Missing	4,320	0.4%	2,403	0.4%	1,045	0.4%	872	0.4%
Vaccine priority groups	HSCW	99,072	8.8%	55,519	9.0%	20,997	7.9%	22,556	9.2%
	At risk***	227,307	20.2%	123,424	20.0%	53,886	20.3%	49,997	20.3%
	CEV	73,997	6.6%	36,067	5.9%	18,517	7.0%	19,413	7.9%
	Severely Immunosuppressed	12,785	1.1%	4,718	0.8%	3,440	1.3%	4,627	1.9%
Previously positive	No	935,434	83.0%	484,592	78.7%	235,170	88.5%	215,672	87.6%
	Yes	192,083	17.0%	131,036	21.3%	30,650	11.5%	30,397	12.4%

*Dose 1 and 2 is recipients of ChAdOx1-S, BNT162b2 or mRNA-1273.

**Booster is recipients of BNT162b2 or mRNA-1273 following any primary immunisation course.

***At risk is only those under 65

Supplementary Table 2. Descriptive characteristics of eligible tests from hospitalised individuals.

			Overall		Negative		BA.1		BA.2	
			n	%	n	%	n	%	n	%
Vaccination Status and intervals after vaccine	Test Result	Interval (weeks)	15,043	100.0%	12,758	84.8%	1,662	11.0%	623	4.1%
	Unvaccinated		940	6.2%	601	4.7%	274	16.5%	65	10.4%
	Dose 1*	<4	20	0.1%	14	0.1%	6	0.4%	0	0.0%
		4+	301	2.0%	217	1.7%	65	3.9%	19	3.0%
	Dose 2*	<2	4	0.0%	4	0.0%	0	0.0%	0	0.0%
		2-24	190	1.3%	162	1.3%	25	1.5%	3	0.5%
		25+	1,270	8.4%	962	7.5%	240	14.4%	68	10.9%
	Booster**	<1	54	0.4%	45	0.4%	9	0.5%	0	0.0%
		1	62	0.4%	54	0.4%	7	0.4%	1	0.2%
		2-4	396	2.6%	362	2.8%	31	1.9%	3	0.5%
		5-9	2,195	14.6%	2,019	15.8%	159	9.6%	17	2.7%
		10-14	4,566	30.4%	4,055	31.8%	403	24.2%	108	17.3%
		15+	5,045	33.5%	4,263	33.4%	443	26.7%	339	54.4%
Age	18-19		32	0.2%	25	0.2%	4	0.2%	3	0.5%
	20-24		102	0.7%	67	0.5%	25	1.5%	10	1.6%
	25-29		144	1.0%	89	0.7%	38	2.3%	17	2.7%
	30-34		194	1.3%	111	0.9%	64	3.9%	19	3.0%
	35-39		218	1.4%	158	1.2%	43	2.6%	17	2.7%
	40-44		238	1.6%	178	1.4%	44	2.6%	16	2.6%
	45-49		335	2.2%	282	2.2%	40	2.4%	13	2.1%
	50-54		492	3.3%	384	3.0%	78	4.7%	30	4.8%
	55-59		644	4.3%	548	4.3%	80	4.8%	16	2.6%
	60-64		896	6.0%	757	5.9%	104	6.3%	35	5.6%
	65-69		1,286	8.5%	1,109	8.7%	125	7.5%	52	8.3%
	70-74		1,707	11.3%	1,461	11.5%	175	10.5%	71	11.4%
	75-79		2,073	13.8%	1,778	13.9%	210	12.6%	85	13.6%
	80-84		2,369	15.7%	2,058	16.1%	218	13.1%	93	14.9%
	85-89		2,333	15.5%	2,041	16.0%	213	12.8%	79	12.7%
	>=90		1,980	13.2%	1,712	13.4%	201	12.1%	67	10.8%
Gender	Female		7,405	49.2%	6,260	49.1%	837	50.4%	308	49.4%
	Male		7,554	50.2%	6,414	50.3%	825	49.6%	315	50.6%
	Missing		0	0.0%	0	0.0%	0	0.0%	0	0.0%
Ethnicity	African		107	0.7%	79	0.6%	22	1.3%	6	1.0%
	Any other Asian background		121	0.8%	92	0.7%	25	1.5%	4	0.6%
	Any other Black background		48	0.3%	34	0.3%	11	0.7%	3	0.5%
	Any other White background		691	4.6%	541	4.2%	107	6.4%	43	6.9%
	Any other ethnic group		155	1.0%	119	0.9%	23	1.4%	13	2.1%
	Any other mixed background		43	0.3%	30	0.2%	11	0.7%	2	0.3%
	Bangladeshi or British Bangladeshi		66	0.4%	44	0.3%	18	1.1%	4	0.6%
	British, Mixed British		12,290	81.7%	10,608	83.1%	1,210	72.8%	472	75.8%
	Caribbean		102	0.7%	68	0.5%	30	1.8%	4	0.6%

	Chinese	38	0.3%	23	0.2%	12	0.7%	3	0.5%
	Indian or British Indian	292	1.9%	228	1.8%	49	2.9%	15	2.4%
	Irish	157	1.0%	134	1.1%	12	0.7%	11	1.8%
	Pakistani or British Pakistani	224	1.5%	169	1.3%	46	2.8%	9	1.4%
	White and Asian	8	0.1%	6	0.0%	1	0.1%	1	0.2%
	White and Black African	15	0.1%	11	0.1%	4	0.2%	0	0.0%
	White and Black Caribbean	26	0.2%	16	0.1%	4	0.2%	6	1.0%
	Missing	660	4.4%	556	4.4%	77	4.6%	27	4.3%
NHS Region	East of England	1,323	8.8%	1,135	8.9%	127	7.6%	61	9.8%
	London	1,618	10.8%	1,248	9.8%	258	15.5%	112	18.0%
	Midlands	3,443	22.9%	2,997	23.5%	326	19.6%	120	19.3%
	North East	2,627	17.5%	2,331	18.3%	234	14.1%	62	10.0%
	North West	2,334	15.5%	1,940	15.2%	321	19.3%	73	11.7%
	South East	2,181	14.5%	1,817	14.2%	247	14.9%	117	18.8%
	South West	1,517	10.1%	1,290	10.1%	149	9.0%	78	12.5%
	Missing	0	0.0%	0	0.0%	0	0.0%	0	0.0%
IMD Quintiles	1	3,618	24.1%	3,075	24.1%	443	26.7%	100	16.1%
	2	3,110	20.7%	2,609	20.4%	361	21.7%	140	22.5%
	3	2,900	19.3%	2,454	19.2%	313	18.8%	133	21.3%
	4	2,870	19.1%	2,455	19.2%	293	17.6%	122	19.6%
	5	2,516	16.7%	2,142	16.8%	246	14.8%	128	20.5%
	Missing	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Vaccine priority groups	HSCW	87	0.6%	56	0.4%	23	1.4%	8	1.3%
	At risk***	2,387	15.9%	1,920	15.0%	347	20.9%	120	19.3%
	Severely Immunosuppressed	1,440	9.6%	1,102	8.6%	259	15.6%	79	12.7%
	CEV	7,659	50.9%	6,399	50.2%	942	56.7%	318	51.0%
Previously positive	No	13,366	88.9%	11,185	87.7%	1,579	95.0%	602	96.6%
	Yes	1,677	11.1%	1,573	12.3%	83	5.0%	21	3.4%
Pillar	1	14,065	93.5%	12,528	98.2%	1,071	64.4%	466	74.8%
	2	978	6.5%	230	1.8%	591	35.6%	157	25.2%

*Dose 1 and 2 is recipients of ChAdOx1-S, BNT162b2 or mRNA-1273.

**Booster is recipients of BNT162b2 or mRNA-1273 following any primary immunisation course.

***At risk is only those under 65

Supplementary Table 3. Vaccine effectiveness estimates against symptomatic disease for individuals aged 18 years and older in England.

Doses	Interval (weeks)	Controls	BA.1		BA.2	
			Cases	VE (95% CI)	Cases	VE (95% CI)
Unvaccinated		37,280	33961	Baseline	25832	Baseline
Dose 1*	<4	2,086	1229	44.6 (40.3-48.6)	366	53.3 (46.9-58.9)
	4+	14,414	7608	38.6 (36.4-40.6)	5617	44.5 (42.2-46.7)
Dose 2*	<2	1,189	434	63.1 (58.5-67.1)	201	64.3 (57.7-69.9)
	2-24	39,555	25444	34.9 (33.4-36.5)	10123	44.9 (43.1-46.6)
	25+	46,958	33616	14.8 (12.9-16.7)	26366	27.8 (25.9-29.7)
Booster**	<1	2,751	1785	44.3 (40.6-47.8)	433	51.2 (45.1-56.6)
	1	5,541	1989	70.6 (68.9-72.2)	379	74.0 (70.8-76.9)
	2-4	51,990	20352	68.7 (68.0-69.5)	2592	74.1 (72.9-75.3)
	5-9	168627	67466	63.5 (62.8-64.2)	25788	66.1 (65.2-66.9)
	10-14	143890	43743	53.0 (52.0-54.1)	69423	59.4 (58.5-60.3)
	15+	101347	28193	37.4 (35.8-39.0)	78949	43.7 (42.3-45.1)

*Dose 1 and 2 is recipients of ChAdOx1-S, BNT162b2 or mRNA-1273.

**Booster is recipients of BNT162b2 or mRNA-1273 following any primary immunisation course.

Supplementary Table 4. Vaccine effectiveness estimates against hospitalisation for individuals aged 18 years and older in England.

Doses	Interval (weeks)	Controls	BA.1		BA.2	
			Cases	VE (95% CI)	Cases	VE (95% CI)
Unvaccinated		601	274	baseline	65	baseline
Dose 1*	<4	14	6	n/a	0	n/a
	4+	217	65	29.8 (-0.2-50.8)	19	12.5 (-60.1-52.2)
Dose 2*	<2	4	0	n/a	0	n/a
	2-24	162	25	76.1 (59.3-86.0)	3	86.3 (52.8-96.0)
	25+	962	240	50.6 (37.7-60.8)	68	25.9 (-11.1-50.6)
Booster**	<1	45	9	60.9 (12.3-82.5)	0	n/a
	1	54	7	82.7 (56.9-93.0)	1	59.7 (-216-94.9)
	2-4	362	31	90.8 (85.1-94.3)	3	82.8 (41.9-94.9)
	5-9	2,019	159	89.1 (85.9-91.5)	17	89.1 (80.5-94.0)
	10-14	4,055	403	85.4 (81.9-88.2)	108	70.2 (56.8-79.5)
	15+	4,263	443	80.4 (75.6-84.3)	339	56.5 (38.4-69.3)

*Dose 1 and 2 is recipients of ChAdOx1-S, BNT162b2 or mRNA-1273.

**Booster is recipients of BNT162b2 or mRNA-1273 following any primary immunisation course.

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